

additional fees associated with this amendment to Deposit Account No. 15-0610.

The specification has been amended to correct clerical errors kindly noted by the Examiner.

The Examiner rejected claims 1-35 under 35 USC § 112, first paragraph, asserting that the disclosure is enabling only for claims limited to the filler being silica. Applicants note in the first instance that this rejection can at most apply to claims 1, 2, 15, 16, 17, 18, 25, 26 (not all of claims 1-35), since all of the other claims expressly recite silica in the claims.

Furthermore, Applicants submit that the Examiner has failed to meet the burden of setting forth a *prima facie* case of non-enablement sufficient to support a rejection.

The sole explanation of the rejection is that “the only example that is disclosed is silica. No other examples have been disclosed showing that all fillers will work in this apparatus.” Controlling case law clearly establishes, however, that examples are not required for enablement. In re Robins, 166 USPQ 552 (CCPA 1970). Furthermore, the burden is on the Examiner to come forward with specific reasons **why** a person skilled in the art would not be enabled to practice the claimed invention. In re Strahilevitz, 212 USPQ 561, 563 (CCPA 1982).

In this case, it appears that the Examiner is questioning Applicants statement that fillers which have both hydrophobic and hydrophilic surface regions will work in the apparatus of the invention. This type of rejection is specifically addressed in *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). In *Marzocchi*, the CCPA stated:

a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in defining and describing the subject matter sought to be patented **must** be taken as in compliance with the enabling requirement of the first paragraph of § 112 **unless** there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

169 USPQ at 369 (emphasis in original). Furthermore, “any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed.” *In re Dinh-Nguyen* 181 USPQ 46, 47 (CCPA 1974). Plainly, the Examiner has failed to meet this standard. The rejection should therefore be withdrawn or, if reiterated, presented in a complete form in a non-

final Office Action.

The Examiner also rejected claims 8-12 and 33-35 under 35 USC § 112, second paragraph, as indefinite. In connection with claims 8-12, the Examiner states that these claims are indefinite because claim 8 contains a trademark or tradename. While, Applicants respectfully submit that there is no *per se* rule prohibiting the use of trademarks in claims, claim 8 has been amended to recite the generic description from Page 10, lines 2-3.

The Examiner also asserts that claims 33-35 are indefinite “with respect to whether the applicant is claiming the apparatus or the method of using the apparatus. It appears that there is no structural features recited in the instant claims as set forth, but instead only process limitations.” Applicants respectfully disagree. Nevertheless, claims 33 and 35 have been amended to include structural features to make it clear that it is the article of manufacture (i.e., the disposable glucose test strip) which is being claimed in each case.

On the merits, the Examiner rejected claims 1-35 under 35 USC § 103 as obvious over US Patent No. 5,565,085 or 5,582,697 of Ikeda in combination with US Patent No. 5,582,698 to Flaherty. The Examiner states that Ikeda discloses an electrode like the one claimed, but lacking in the filler, and that Flaherty discloses the use of a silica filler in a semipermeable membrane. Based on these two disclosures, the Examiner asserts that adding a silica filler to the working coating of Ikeda would have been obvious. Applicants respectfully disagree.

In order to support an obviousness rejection based on a combination of references, the references relied upon must, without resort to Applicants’ specification for guidance, provide a suggestion to make the modifications of the prior art necessary to arrive at the Applicants’ claimed invention. Shopping through the prior art to find the pieces of the invention is not allowed. Furthermore, the properties of that claimed invention must be those which the person skilled in the art would have expected. In this case, the Examiner has used art which the ordinary artisan would not have combined, and ignored the surprising properties of the claimed invention as demonstrated in the application. Applicants therefore submit that the rejection is in error and should be withdrawn.

The Ikeda patents disclose single-use biosensors, including glucose sensors, in which a reactive layer is formed in the surface of an electrode. This reactive layer contains an enzyme, and electron acceptor and carboxyethyl cellulose. In use, a liquid sample is placed in contact with the reactive layer **causing it to dissolve**. (Col. 4, line 34-36). Reaction between the components of the dissolved reactive layer and glucose results in a transfer of electrons to the underlying electrodes., thus generating a current indicative of the amount of glucose in the sample.

The Flaherty patent discloses a multi-use electrode system, in which an outer protective membrane is disposed over the surface of the reactive layers of the electrode. This membrane is made from organic silicones combined with an alkali metal silicate or colloidal silica. It does not dissolve on contact with a liquid sample, but instead creates a barrier between the bulk of the sample and the underlying reactive layers.

The Examiner has argued that because silica is a required component of the semi-permeable membranes, it would have been obvious to include silica in the coatings of Ikeda for the same benefits, i.e., strength and storage stability of the silicone-containing emulsion. A very relevant question, however, is why a person skilled in the art would have considered such properties to be beneficial in the context of the Ikeda device. The reactive layer in Ikeda is intended to dissolve in order for the device to work. Giving this layer strength (of the type desired for a semipermeable membrane) so that it would not dissolve is not something the person skilled in the art would consider obvious. Furthermore, silica is included in the compositions of Flaherty because of the interaction between silica and the organic silicones which make up the emulsion from which the semipermeable membrane is formed. There are no organic silicones in the Ikeda composition, nor any emulsion to be stabilized. Thus, the very purpose for which silica is used in Flaherty is irrelevant to the Ikeda device. This being the case, the combination of the art as suggested by the Examiner would not have been not obvious.

Moreover, the compositions of the present invention provide surprising advantages not found in prior art devices. These include the fact that the response of this test strip is dependent on the diffusion rate of glucose, not on the rate at which the enzyme can

oxidize glucose, such that the performance of the test strip is essentially temperature independent over relevant temperature ranges. Further, the silica appears to form a two-dimensional network which excludes red blood cells, thus rendering the test strip substantially insensitive to the hematocrit of the patient. These important advantages could not be predicted from the prior art, and thus stand as evidence of the non-obviousness of the invention.

Because the basic rejection of the claims is flawed. Applicants will not, in the interest of brevity, address at this time the assertions made by the examiner concerning the dependent claims. This does not mean that Applicants agree with or admit any of the assertions made by the Examiner.

In view of the foregoing remarks, Applicants submit that all of the pending claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,



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